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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/821,025	03/19/1997	HENDRIK LOUIS BIJL	GRT/4662-399	3574
23117 7590 05/09/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/821,025	Applicant(s) BIJL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 68,72,76-96 and 113-116 is/are pending in the application.
- 4a) Of the above claim(s) 96 and 113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68,72,76-95 and 114-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/07 has been entered.

Claims 68, 72, 76-95 and 114-116 are being considered on the merits.

Claims 96 and 113 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 78-79 and 114-116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a granule comprising extruded *Mortierella* comprising a polyunsaturated fatty acid that is a C18, C20 or C22 ω -3-polyunsaturated fatty acid or a C18, C20 or C22 ω -6-polyunsaturated fatty acid. *Mortierella* is disclosed as producing Gamma-Linolenic Acid (GLA), C18- ω 6, Dihommo Gamma-Linolenic Acid (DGLA) C20 ω -6 and/or Arachidonic Acid (ARA), C20 ω -6.

In addition, no clear basis or support is found in the present specification for dried granules of *Mortierella* comprising arachidonic acid and having an average dry matter content of 80% or more as in claim 114.

Moreover, no clear basis or support is found in the present specification for dried granules of *Mortierella* having an average dry matter content of 80% or more, comprising arachidonic acid and wherein the porosity is 15-50% as now recited in claim 116.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 is incomplete in depending on a cancelled claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68, 72, 76-80, 83-95 and 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto *et al.* (U.S. Patent No. 4,916,066) taken with Barclay MO(U.S. Patent No. 5,656,319) and Huang *et al.* (U.S. Patent No. 4,056,38) and further taken with Langejan (U.S. Patent No. 3,843,800) and Groenendaal (U.S. Patent No. 5,716,654)

Akimoto *et al.* teach a dry *Mortierella* composition (See, e.g., col. 8, lines 7-12). The reference differs from the claimed invention in that the dried composition is not in extruded granule form. However, Barclay teaches a related microbial composition containing fatty acids wherein the composition is extruded. See, e.g., bridging paragraph between col. 11 and 12.. The reference recognizes the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion. In addition, Huang *et al.* teach extruded granules of fungi such as *Aspergillus* which are subsequently dried. See, e.g., bridging paragraph between col. 2 and 3, and col. 3, lines 11-17.

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The extruded material would reasonably be expected to be porous as claimed, to have the degree of dryness required and to have the dimensions as claim designated.

In addition, Langejan teaches a dry yeast preparation prepared by extrusion and having the required dimensions and porosity. See, e.g., Example 1. The yeasts in this preparation are active initially, but as indicated by Groenendaal lose activity and are dead. See, e.g., col. 1, lines 45-67.

The properties of the dried *Mortierella* as far as oil content and sizing discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of composition properties for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Inasmuch as Langejan discloses a fungal product that is granular, porous and has the appropriate dimensions, one of ordinary skill in the art would reasonably have expected that similar extruded products containing other fungi, such as *Mortierella*, that are known producers of important fatty acids, as disclosed by Barclay, would similarly provide the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the dried *Mortierella* product of Akimoto *et al.* by submitting the biomass to an extrusion and drying process as disclosed by Barclay, Huang *et al.*, Langejan and Groenendaal in view of the expected economic benefits of obtaining a dried stable microbial product that is easy to manipulate and the cost of which is reduced.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that none of the references indicate that the granules have a diameter between 0.1 and 12 mm and that this sizing is significant because applicant disclose that the granules should not be too small or too large. However, Langejan discloses a diameter of 0.4

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mm. Moreover, no clear definition of the optimum size for the granules is found in the disclosure. As a matter of fact, from claim 90 as written it is apparent that a “granule” of 12 mm diameter and 72 mm in length is envisioned. Thus the claimed invention ranges from granules that are, for example, 0.1 mm in diameter to 0.2 mm long to those that are 12 mm diameter and 72 mm long.

As to the specific porosity argued, the claims 91-93 are not related to solvent access as argued. This is claimed in claim 94. Moreover, it is unclear all dead *Mortierella* necessarily comprise extractable products as argued, particularly as claimed in claims 78 and 79. See the new matter rejection, *supra*. In addition, the preparations of Langejan are highly porous. See, e.g., Groenendaal col. 1, lines 56-57.

The arguments regarding Example 25 are noted. However, Example 1 cited does not include an extrusion procedure. Moreover, it is unclear that the touted results of Example 25 pertain with any specificity to the invention as claimed in the independent claims. At least in claim 68 there is no indication of any polyunsaturated acid content in the dried granules. Moreover, the porosity in this example is 27-30%

Inasmuch as Langejan discloses a fungal product that is granular, porous and has the appropriate dimensions, one of ordinary skill in the art would reasonably have expected that similar extruded products containing other fungi, such as *Mortierella*, that are known producers of important fatty acids, as disclosed by Barclay, would similarly provide the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In *re Dill*, 202 USPQ 805 (CCPA, 1979), In *re Lindner* 173 USPQ 356 (CCPA 1972), In *re Hyson*, 172 USPQ 399 (CCPA 1972), In *re Boesch*, 205 USPQ 215, (CCPA 1980), In *re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983), In *re Clemens*, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

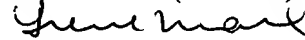
Therefore the rejection is deemed proper and it is adhered to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
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